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### **REMARKS**

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

At the outset, Applicants thank the Examiner for her courtesy in granting Applicants an interview on August 27, 2002.

#### **1. SUMMARY OF THE OFFICE ACTION**

As correctly indicated in the Office Action, claims 35-57 (as renumbered) are pending. The Examiner has indicated that claims 35-51 stand rejected and that claims 52-57 are withdrawn from consideration.

Applicants note with appreciation that the Examiner has renumbered original claims 41-58 to 40-57 given that there was no claim 40.

#### **2. SUMMARY OF THE RESPONSE**

Applicants have amended the specification at pages 1, 2-4, 5 and at page 6 to correct grammatical errors and duplications.

Applicants have amended claim 35 without prejudice or disclaimer as to the subject matter claimed therein. Claim 35 has been amended to more distinctly recite the subject matter of the invention. Support for the amendments to claim 35 can be found at least in the claims as originally filed in the PCT and in the specification at least at page 3, lines 11-13 ("TNF- $\alpha$  activity"). Applicants reserve the right to file a continuation or divisional application on the subject matter canceled by way of the amendments.

Applicants submit new claim 58, which has support in the specification at least in the originally filed claims.

None of these amendments are believed to introduce any prohibited new matter.

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3. **ACKNOWLEDGEMENT OF IDSs**

Applicants appreciate the acknowledgment and return of the 1449 forms received by the Office on August 9, 2001 and April 8, 2002. As indicated by the Applicants during the interview, acknowledgment of two IDS remain. Specifically, Applicants submitted an IDS on January 17, 2001 when the national stage application was filed. Another IDS was submitted to the Office on June 28, 2002 (after the mailing of Paper No. 8) for which Applicants also expect acknowledgment.

4. **ELECTION/RESTRICTION**

Applicants note that the restriction and election have been made final, despite Applicants' traversal. Applicants further assert that this finding is in direct contradiction with PCT rules and with the guidelines set forth by the U.S. Patent and Trademark Office. For example, Applicants turn the Examiner's attention to M.P.E.P. § 1895.01(D), which explicitly states that: "[r]estriction practice under 35 U.S.C. 121, as it applies to national applications submitted under 35 U.S.C. 111(a), is *not applicable* to either international or national stage applications." [Emphasis added]. Thus, to enforce a restriction on the instant claims violates this policy. Accordingly, Applicants again respectfully request withdrawal of the restriction set forth in the paper mailed January 11, 2002 (Paper No. 5).

5. **PRIORITY STATEMENT**

The Examiner asserts that the priority statement added under CROSS-REFERENCED APPLICATIONS on page 1 of the Amendment filed January 17, 2001 should be deleted, because applications filed under §371 purportedly should not have this information in the specification. Applicants respectfully traverse this objection.

Applicants turn the Examiner's attention to 37 C.F.R. § 1.78 (a)(2) which states the following:

. . . , any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America *must contain or be amended to contain in the first*

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*sentence of the specification following the title a reference to each such prior application, identifying it by application number...or international application number and international filing date and indicating the relationship of the applications . . . . (Emphasis added)*

Accordingly, the priority statement added by the Preliminary Amendment dated January 17, 2001 is proper. However, Applicants agree with the Examiner's observation that the information is duplicative. Applicants have amended the priority statement such that the first two lines as seen in the Preliminary Amendment are now omitted, thereby obviating the redundancy.

The Office further asserted that the Applicants have not filed a certified copy of the 9803276-6 application as required by 35 U.S.C. § 119(b). Applicants respectfully assert that under 35 U.S.C. § 371, there is no duty to supply a certified copy of the prior foreign filed priority applications (in this case there are two Swedish priority applications) in national stage applications filed under 37 C.F.R. § 371. Applicants direct the Examiner's attention to M.P.E.P. § 1828: "The International Bureau will normally furnish copies of the certified copy to the various designated offices so that the applicant will not normally be required to submit certified copies to each designated Office." See also M.P.E.P. §§ 1893.03(c) and 1896 (Chart of Some Common Differences).

At this time, Applicants provide non-certified copies of both Swedish priority documents as a courtesy to the Office in an effort to expedite prosecution.

#### 6. DOUBLE PATENTING

The Examiner has made a non-statutory double patenting rejection of claims 35-51 under the judicially created doctrine of obviousness-type double patenting over claims 3-18 of co-pending application No. 09/760,811.

In order to expedite an allowance, Applicants submit a Terminal Disclaimer to obviate a provisional double patenting rejection over a second pending application, U.S. Serial No. 09/760,811. The attached Terminal Disclaimer thereby overcomes the provisional rejection.

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7. **SPECIFICATION INFORMALITIES**

Several informalities were objected to by the Examiner in the specification. Applicants discuss them in the order in which they were raised.

First, regarding the first complete sentence appearing at page 5, line 1:

"To assess if TNF- $\alpha$  may be involved in the nucleus pulposus induced nerve root injury the presence of TNF- $\alpha$  in nucleus pulposus-cells was assessed and was studied if the nucleus pulposus-induced effects could be blocked by doxycycline, a soluble TNF-receptor, and a selective monoclonal TNF-antibody, the latter administered both locally in the nucleus pulposus and systemically."

Admittedly, the sentence is grammatically incorrect. However, in view of the remainder of the disclosure, the meaning of the sentence would be apparent to one of ordinary skill. Nevertheless, in an effort to correct certain of the spelling and grammatical errors found through the specification, Applicants have amended the above sentence, as well as other portions of the paragraph as indicated in the marked up copy. As amended, the sentence is not believed to introduce any prohibited new matter.

Second, Applicants note that "gl" is a typographical error. It should instead be " $\mu$ l." The use of the term "gl" is clearly incorrect. Additionally, the unit of "microliter" would be evident to an artisan of ordinary skill given the reference to antibodies. Microliter quantities are commonly used given expected antibody affinities and aridities. A milliliter amount would be rare as would be nanoliter, the next unit less than  $\mu$ l using the Système International (SI) units of measurement.

Third, the Examiner noted the use of "1,11" which should be "1.11". This has been amended with the instant reply thereby obviating the rejection.

7. **REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 35-51 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite. Specifically claim 35 was rejected because the first line states "treating nerve disorders" and the last line recites "inhibits nerve injury", which is asserted as different. Claim 35 was further rejected as indefinite for use of the term "blocks".

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Applicants have amended claim 35 to remove "inhibits nerve injury" and recite in its place "treats a nerve disorder" placing the claim in symmetry with the first line of the claim. Applicants have also amended claim 35 with the addition of the word "activity" after "TNF- $\alpha$ " as courteously suggested by the Examiner.

As the amendments moot the rejection, Applicants respectfully request withdrawal of the rejection.

### CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Date: August 30, 2002